

REMARKS

This paper is responsive to the non-final Office Action mailed January 16, 2009. In the Office Action, all claims 1 and 3-32 were rejected. Claims 4, 23, 24, 30 and 31 have now been canceled.

Rejections under 35 USC §102(b).

Claims 1, 3, 9, and 12-17 stand rejected under 35 USC §102(b) as anticipated by Cox (USP 4,340,046).

Claim 1, as amended herein, is directed to a tracheostomy tube comprising a hollow tubular body having a proximal end portion, a distal end portion and a curved portion intermediate the proximal and distal end portions. The hollow tubular body includes a collar at its proximal end, the collar having a groove. A flange is situated at the proximal end portion of the tubular body. The flange is capable of selective attachment to the tubular body and removal therefrom. The flange extends radially from the proximal end portion when attached thereto, and includes a cut-away portion extending radially inwardly from a lateral side thereof. The cut-away portion and the groove are cooperatively sized and shaped to mate when the flange is attached to the tubular body.

According to the Examiner, the newly-cited reference to Cox teaches a trach tube including a removable flange situated at a proximal portion of the tube. As noted above, claim 1 has been amended to include the limitations from claim 4 relating to the tube including a collar at its proximal end, wherein the collar includes a groove for mating with a cut-away portion of the flange. Claim 1 has also been amended to specify that the cut-away portion extends laterally inwardly from a lateral side of the flange. The Examiner acknowledged (page 5 of the OA) that Cox is silent as to a collar with a groove for mating with a cut-away portion of the flange. Therefore, Cox cannot anticipate amended claim 1, or the claims depending therefrom.

Claim 12, as amended herein, is directed to an insertion device comprising a tracheostomy tube and a loading dilator. The tracheostomy tube has a longitudinal bore and a tapered distal tip. The loading dilator has a larger-diameter stepped proximal portion and a smaller diameter distal portion extending from the larger diameter

proximal portion. The smaller diameter distal portion has a generally cylindrical profile, wherein the generally cylindrical profile tapers to a tapered distal end. The smaller-diameter distal portion is sized to be insertable through the longitudinal bore of the tracheostomy tube such that the tapered distal end extends axially beyond the tapered distal tip of the tracheostomy tube.

Among other things, Cox does not include a loading dilator having a larger-diameter stepped proximal portion and a smaller diameter distal portion extending from the larger diameter proximal portion, wherein the smaller diameter distal portion has a generally cylindrical profile, and the generally cylindrical profile tapers to a tapered distal end. The Examiner has referenced a larger diameter portion of obturator 18 having a distal guide nub 72 as meeting this limitation. However, it is clear the generally cylindrical, smaller diameter main shaft means 68 of Cox does not taper to a tapered distal end. Rather, larger diameter nub 72 is the portion of Cox that tapers. In the present claim, the cylindrical profiled portion is the portion of the shaft that tapers. Therefore, Applicant submits that Cox cannot anticipate claim 12, or the claims depending therefrom.

In addition to the foregoing, Applicant points out that there is no suggestion in Cox to provide a taper to a smaller diameter portion as claimed herein. Providing the taper as claimed herein enables the physician to conveniently insert the tracheostomy tube into the trachea using the combined tracheostomy tube/loading dilator, wherein a smooth tapered distal profile results therefrom. No suggestion of this feature is provided in Cox.

Rejections under 35 USC §103(a).

Claims 4-7 were rejected under 35 USC §103(a) as being unpatentable over Cox as applied to claims 1, 3, 9 and 12-17, and further in view of Stuart (USP 5,778,877). As stated above, the Examiner acknowledged that Cox (USP 4,340,046) is silent as to a collar with a groove for mating with a cut-away portion of the flange. The Examiner also acknowledged that Cox is silent as to snap-fitting with a receptacle on the tubular body.

Amended claim 1, as recited above, includes the limitation that the flange includes a cut-away portion extending radially inwardly from a lateral side thereof, the

cut-away portion and the groove being cooperatively sized and shaped to mate when the flange is attached to the tube. By providing a cut-away portion that extends radially inwardly from a lateral side of the flange, the flange can easily mate with the groove in the collar by a snap-fit or other attachment means. This arrangement facilitates use of the removable flange by providing a rapid and convenient means for attachment and removal. Neither Cox nor Stuart teaches or suggests such an arrangement.

Claims 5-7 (claim 4 has been canceled) are dependent from claim 1, and therefore include all of its limitations. The secondary Stuart reference supplies none of the elements missing from Cox, including the feature of a flange cut-away portion extending laterally inwardly from a lateral side of the flange.

As stated at page 2 of the present application, when an introducer sheath has a flange or other extension member projecting radially from the body of the device, difficulties can be encountered when attempting to withdraw the introducer sheath from the body opening following insertion of the tracheostomy tube. In such a case, the flange portion of the tube is situated directly in the path of the withdrawing sheath, thereby obstructing the withdrawal of the sheath. The tracheostomy tube having a laterally removable sheath as claimed herein removes this impediment, by allowing the user to remove the flange until the sheath has been withdrawn, thereby facilitating withdrawal of the introducer sheath. As shown in Fig. 4, by providing the cut-away portion that extends radially inwardly from a lateral side of the flange, the flange can be easily snapped onto, and off of, the tracheostomy tube.

The Examiner stated that Stuart has a collar with a groove for mating (34, 36) for cooperatively engaging a flange cut-away portion. However, the structure in Stuart recited by the Examiner is annular with an opening in the center. Neither Cox nor Stuart teaches a flange which may be selectively attached and removed from the tracheostomy tube by simply sliding it onto, or off of, the tracheostomy tube. The combination cited by the Examiner would be cumbersome and difficult to use in the inventive structure, if possible at all.

Claims 18-21 were rejected under 35 USC §103(a) as being unpatentable over Cox. Claims 18-21 depend, directly or indirectly, from independent claim 12, and therefore include all of its limitations, including the limitations referenced

above related to a loading dilator having a larger-diameter stepped proximal portion and a smaller diameter distal portion, wherein the smaller diameter distal portion tapers to a tapered distal end. Cox does not teach or suggest this arrangement. Thus, these claims are believed allowable over Cox for at least the same reasons that claim 12 is allowable.

Claims 8 and 22-29 were rejected were rejected under 35 USC §103(a) as being unpatentable over Cox as applied to claims 1, 3, 9, and 12-17, and further in view of Varner (USP 6,105,577).

Claim 8 is dependent from claim 1, and is believed patentable for at least the same reasons that claim 1 is patentable. The secondary Varner reference supplies none of the elements missing from Cox, and most particularly, does not supply the feature of a flange cut-away portion extending laterally inwardly from a lateral side of the flange.

Claim 22 has been amended to generally incorporate the limitations of claims 23 and 24. As amended, claim 22 is directed to a device for percutaneous insertion into the trachea of a patient. The device includes a tracheostomy tube having a longitudinal passageway therethrough. The tracheostomy tube has a distal end portion percutaneously insertable into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted. The tracheostomy tube further has a radially extending flange capable of selective attachment to and removal from the tracheostomy tube after the distal end portion has been inserted into the trachea. A dilator is positionable within the longitudinal passageway of the tracheostomy tube for dilating an opening in the trachea for insertion of the tracheostomy tube. A locking assembly is provided for locking the tracheostomy tube to the dilator during insertion of the tracheostomy tube into the trachea. The locking assembly comprises a securement member associated with the dilator, wherein the securement member is engageable with a complementary member on the tracheostomy tube. The locking assembly further comprises a stop member disposed on an outer surface of the dilator. The stop member is engaged with the dilator such that substantial axial movement of the stop member along said dilator is prevented when an axial force is applied to the stop member. The stop member is positioned on the outer surface and engageable with the

securement member and the complementary member for preventing excess penetration of the tracheostomy tube into the trachea.

In the Office Action (page 6), the Examiner acknowledged that Cox is silent as to a locking assembly for locking the trach tube to the dilator during insertion of the trach tube. Varner was cited for disclosing an inner cannula including locking means for securing the tube to the trach tube. Therefore, according to the Examiner, it would have been obvious to include the locking means of Varner in the dilator of Cox to secure the dilator to the trach tube during insertion "so that the tapered distal tip didn't actually slip axially up into the trach tube."

Applicant respectfully disagrees. First, Applicant respectfully points out that an inner cannula cannot be reasonably equated to a dilator in the claimed structure described above. In fact, as stated in the present application, the inventive structure may be provided with an optional inner cannula (page 12, lines 5-6), which is a different structural feature than the dilator referenced in the claim. One skilled in the art would not equate features provided with an inner cannula with features on a dilator, as the respective devices are very different, both structurally and functionally.

In addition to the foregoing, Applicant submits that the Examiner has combined two disparate references to elicit a solution to a problem that neither of the references has addressed. When a tracheostomy tube as described herein that does not have a neck flange attached is inserted into the trachea of a patient using an introducer sheath, it would be possible to inadvertently insert the tracheostomy tube too far into the body opening. Normally, the presence of the flange on a conventional tracheostomy tube prevents excessive penetration of the tube into the trachea. However, when using a tracheostomy tube having a removable flange as described hereinabove, the flange will not normally have been attached to the tube at the time that the tube is introduced into the body (to permit easy removal of the introducer sheath following insertion of the tracheostomy tube). Therefore, without the presence of the flange to prevent undue penetration, the tracheostomy tube might inadvertently be inserted an excessive distance into the trachea. If this occurs, there is often no convenient way to retrieve the tube without causing additional trauma to the patient.

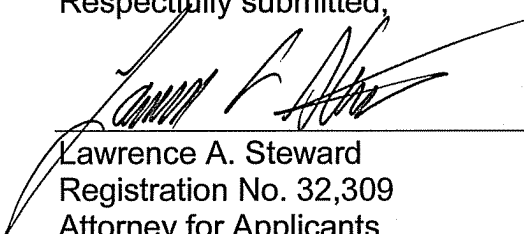
If the tracheostomy tube is inadvertently inserted too far when the dilator and tracheostomy tube are connected utilizing the claimed structure, the physician can retrieve the tracheostomy tube from the body by simply pulling back on the loading dilator. Once tracheostomy tube is in proper position in the body, the securement cap can be disconnected from the tracheostomy tube. The loading dilator and the securement cap can then be removed in tandem, and the attachable flange can be connected to the tracheostomy tube.

Thus, as stated, by providing a lock mechanism for locking the tracheostomy tube and the dilator as claimed, excess penetration of the tracheostomy tube can be prevented. The Examiner has identified the gripping teeth (130) of Varner as meeting the limitation of a securement member (130) of a locking mechanism. This structure is considerably different from the securement member/stop mechanism of the present invention, and cannot be readily transformed into the claimed structure without the exercise of inventive effort, as well as wholesale reconstruction. Nothing in Cox and/or Varner teaches or suggests to the skilled artisan a solution to the problem of excess tracheostomy tube penetration as described above. For the foregoing reasons, reconsideration is respectfully requested.

Conclusion.

For the reasons provided hereinabove, Applicants respectfully submit that all remaining claims 1, 3, 5-22, 25-29, and 32 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution may be advanced by a telephone conversation, the Examiner is respectfully requested to telephone the undersigned attorney.

Respectfully submitted,



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